NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Testimony of:

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To:

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Committee on Small Business
Subcommittee on Investigations and Oversight

On:

Competitive Bidding for Durable Medical Equipment: Will Small Suppliers be able to Compete?

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INTRODUCTION

Chairman Altmire, Ranking Member Gohmert, and Members of the Subcommittee, my name is Jose F. Navarro and I am a member of the Board of Directors of Navarro Discount Pharmacies, which operates 20 pharmacies in Florida. I am also a member of the National Association of Chain Drug Stores' (NACDS) Board of Directors. NACDS represents chain pharmacies with stores numbering from four to over 6,000. Regardless of their size, all NACDS members are deeply concerned about the impact of the competitive acquisition program on patient access.

Thank you for the opportunity to share our thoughts and concerns about the impact of the competitive acquisition program for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) on small businesses. The DMEPOS competitive acquisition program was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Currently, the program, which is limited to 10 metropolitan statistical areas (MSAs), including Miami, where 19 of our pharmacies are located, includes bidding for ten categories of medical equipment and supplies.

Durable medical equipment includes such items as diabetic testing supplies and monitors, walkers, hospital beds, wheel chairs and oxygen tents. Many Medicare beneficiaries obtain these supplies from their local pharmacies. In fact, a recent study conducted by HealthPolicy R&D found that nearly two-thirds of older diabetic patients obtain their diabetes test strips from their retail-based community pharmacies.[1] Retail pharmacies are the largest providers of DMEPOS services to Medicare patients and are in a unique position to assist patients with their care and treatment and to monitor disease trends and therapy outcomes. In many cases, a pharmacist is the most readily accessible healthcare provider in the community for the Medicare beneficiary. One-on-one patient-pharmacist consultations often provide the first opportunity to identify chronic illnesses, and these consultations often result in early detection, referral, and treatment. In addition to helping to preserve the patient's health, early detection and treatment provides tremendous savings for the Medicare program. Continued participation of pharmacies in serving Medicare patients should therefore be an important consideration in the DMEPOS competitive acquisition program.

However, some of the provisions of the competitive acquisition program and other rules proposed by the Centers for Medicare and Medicaid Services (CMS) for DMEPOS suppliers will prevent pharmacies from effectively serving their Medicare patients. We offer our thoughts to help the Subcommittee address certain flaws in the competitive acquisition program. First, the competitive acquisition program's requirement for supplier accreditation creates significant administrative and financial burdens on small pharmacies. Second, diabetes testing supplies sold at retail pharmacies should not be subject to the competitive acquisition program. Third, the expansion of the program to establish national or regional competitive bidding areas for mail-

[1] HealthPolicy R&D, *Medicare's New Competitive Acquisition Program for Durable Medical Equipment: Policy Considerations Involving Beneficiaries with Diabetes, Community-Based Retail Pharmacies and Blood Glucose Monitoring,* Washington, DC, January 2006.

order suppliers could limit participation by small pharmacies and reduce patient access to needed DMEPOS supplies and services. Fourth, CMS' proposed $65,000 surety bond requirement, layered onto the already onerous requirements of the competitive acquisition program, could make it even more difficult for small pharmacies to continue serving Medicare patients' DMEPOS needs.

SUGGESTIONS TO IMPROVE DMEPOS COMPETITIVE ACQUISITION PROGRAM

State-licensed retail pharmacies should be exempt from the accreditation requirement.

The competitive acquisition program requires suppliers to be accredited before they are awarded a contract. The goal of this requirement is to reduce fraud, waste and abuse in the Medicare program. While we stand with CMS in eliminating fraud, waste and abuse from the Medicare program, we do not believe that requiring the accreditation of state-licensed pharmacies will accomplish this goal. CMS has at its disposal a variety of tools to ensure integrity in the Medicare program; however, accreditation of state-licensed pharmacies, as required by the competitive acquisition program, is an unnecessary requirement that could threaten patients' access to DMEPOS supplies from their most accessible provider.

While requiring accreditation of pharmacies is unlikely to reduce fraud, waste and abuse, it may have the result of reducing the number of pharmacies that are available to supply durable medical equipment and supplies to Medicare beneficiaries. The cost associated with the accreditation process, which can amount to several thousand dollars and hundreds of man-hours for each pharmacy, creates a tremendous financial barrier for pharmacies to participate in the program. Pharmacies already struggle to minimize operational expenses to remain competitive in the marketplace, and are skeptical of the accreditation process because even if they undergo the accreditation process, they have no guarantees that they will ultimately be allowed to participate in the DMEPOS program.

In the regulatory impact statement issued with the DMEPOS competitive acquisition final rule, CMS estimated that approximately 15,973 bidding suppliers would participate in the first round, of which 9,584 (about 60 percent) would be awarded a contract.[2] However, at a recent Program Advisory and Oversight Committee meeting, CMS stated that only about 2,200 locations have applied for accreditation.[3] It is important to note that this number represents actual locations and not individual companies that have applied to become accredited for the first round. The expenses and onerous requirements related to the accreditation process are likely largely to blame for the lack of a robust bidder pool in the first round.

[2] Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 72 Fed. Reg. 18081 (April 10, 2007).
[3] Program Advisory and Oversight Committee Meeting, October 11, 2007, Baltimore, Maryland.

In response to concerns raised by small suppliers, CMS has stated that small suppliers will have an opportunity to participate in the competitive acquisition program by creating a small supplier target.[4] However, given that only 2200 suppliers applied for accreditation for the first round, it is reasonable to expect that the number of retail pharmacies that are ultimately awarded contracts for any product category could be very low. As a result, Medicare beneficiaries could face tremendous disruptions in their care as small pharmacies that were unable to cope with the accreditation costs or were not awarded contracts are forced to stop serving Medicare patients.

Further, accreditation, as required of state-licensed pharmacies, is superfluous. Pharmacies are licensed by the board of pharmacy of their respective states to provide services to patients. As part of their licensing process, pharmacies submit to rigorous evaluation of their operations and compliance programs related to pertinent federal and state laws. Further, state pharmacy laws mandate that each pharmacy have a designated pharmacist who is responsible and accountable for the operation of that pharmacy in compliance with appropriate laws and regulations. Today's pharmacists are highly educated, licensed experts in the use of medications and medical devices who advise patients and healthcare providers. These pharmacists are ideally situated to provide Medicare patients using diabetes supplies and other DME items with appropriate counseling and information on the proper use of these items. These qualifications clearly distinguish pharmacies and pharmacists from other unlicensed and unregulated suppliers.

Diabetes testing supplies sold at retail pharmacies should not be subject to competitive acquisition.

Currently, Medicare beneficiaries can obtain their diabetic glucose monitors and testing supplies from any retail pharmacy that participates in the Medicare program, allowing beneficiaries to obtain all of their covered equipment, supplies, and prescription drugs for managing their diabetes from a qualified pharmacist. As mentioned earlier, the majority of older diabetic patients rely on their retail pharmacies for their diabetic supplies. Evidence shows that pharmacist-based programs can result in clinically significant improvements in health outcomes for diabetic patients. Through programs such as the "Asheville Project," the pharmacy setting has been shown to provide a successful platform for initiatives to improve adherence to testing and treatment regimens for patients with diabetes.[5] Other private and public healthcare programs have also placed the pharmacist in a central role in the management of diabetes and other chronic diseases. It would be ill-advised to risk disrupting these pharmacist-patient relationships while further experience is being gained in the effectiveness of community-based pharmacies in promoting adherence to blood glucose treatment and monitoring regimens.

Unlike other DME supplies, CMS did not evaluate the effects of competitive acquisition on diabetes supplies during the competitive bidding demonstration projects. Thus, expansion of the competitive acquisition program to diabetes supplies sold at retail pharmacies will create

[4] Note 2 at 18044.
[5] Pharmacy Times, *The Ashville Project: A Special Report* (October, 1998), *available at* http://www.pharmacytimes.com/files/articlefiles/TheAshevilleProject.pdf.

significant confusion and frustration to diabetic patients and their providers. At a time when Medicare is attempting to move away from fragmented care, competitive acquisition is likely to interfere with patient access and could adversely affect diabetes management.

Further, the study conducted by HealthPolicy R&D examined issues related to competitive acquisition of diabetic products and associated services under Medicare Part B and noted the following:

- Costs to the Medicare program will increase if access to the full range of monitoring options is lost or if the frequent in-person counseling by retail pharmacists is disrupted.
- The complexity of using glucose monitors, particularly for an elderly beneficiary, is a major concern. Pharmacists play an important role in helping beneficiaries select the optimal monitors and in the correct use of such monitors, both in terms of initial instruction and subsequent reinforcement of that instruction over time. Much of the professional support originates from the ongoing relationship between beneficiaries and pharmacists.
- CMS excluded blood glucose monitors and supplies from the DME competitive bidding demonstration project, due, in part, to concerns regarding the complexity of matching glucose monitors with the appropriate testing supplies.
- The competitive acquisition program could operate contrary to Medicare's current and future initiatives that are designed to promote adherence to blood glucose regimens and reduce overall costs in managing diabetes.

CMS should not create national or regional competitive acquisition areas for mail-order items.

In the competitive acquisition final regulation, CMS stated that, for the year 2010 and thereafter, it has the authority to establish national or regional competitive acquisition areas for suppliers that furnish items through mail-order. As I have already shared with the Committee, the majority of older patients prefer to obtain DME supplies for conditions such as diabetes from their local pharmacist with whom they have an ongoing relationship. The presence of a licensed pharmacist at their community retail pharmacy gives patients the opportunity to discuss proper use of the DMEPOS items with their pharmacist. This individualized attention is critical to increasing patient compliance with therapy regimen and improving health outcomes, particularly with chronic disease such as diabetes. The benefit of such interaction should not be taken lightly as it provides a valuable patient care forum for early awareness and treatment of diseases, and translates into substantial savings for the Medicare program.

Creation of a regional or national mail-order program may produce an additional disincentive for small providers to participate in the program as the contracts are likely to be awarded on the basis of price alone. As a result, patients may find it even more difficult to gain access to the community pharmacist they trust, eroding the benefits of the pharmacist-patient relationship shown to improve health outcomes and reduce healthcare spending.

State-licensed retail pharmacies should be exempt from CMS' proposed surety bond rule.

During the midst of competitive acquisition program implementation, CMS also proposed to require a $65,000 surety bond from all Medicare DMEPOS suppliers. As if the costs associated with accreditation and bidding did not create enough disincentives for small suppliers, CMS' proposal to require a surety bond is likely to keep many interested suppliers from participating.

In its proposal, CMS estimated that annual administrative costs related to the surety bond would be $2000.[6] For many DMEPOS suppliers, the administrative fees required in obtaining the surety bond could be prohibitive as such fees may not be recouped even through their total annual Medicare billing. Ultimately, small DMEPOS suppliers, particularly those serving rural and underserved areas, may be unable to cope with the recurring and rising administrative costs in providing DMEPOS services and may be forced to turn away Medicare beneficiaries.

According to CMS' own calculation, up to 15,000 DMEPOS suppliers currently enrolled in Medicare (22 percent of whom are in rural areas) could cease providing items to Medicare beneficiaries as a result of the surety bond.[7] CMS envisions that, "most, if not all, of the Medicare business conducted by these DMEPOS suppliers would be assumed by other DMEPOS suppliers remaining in the program (for example, by mail-order order or via the World Wide Web)."[8] Clearly, CMS indicated that this proposed rule will result in even fewer small pharmacies participating in the Medicare DMEPOS program. As a result, patients could face tremendous difficulties in obtaining their necessary DMEPOS items and services.

CONCLUSION

I am grateful for the opportunity to testify before you today. Thank you for providing a forum to air our concerns about the DMEPOS competitive acquisition program. If sufficient protections are not offered for retail pharmacies and their patients, Medicare beneficiary access to DMEPOS items and pharmacy assistance in using those items will be reduced, and Medicare Part B spending will likely increase.

[6] Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 72 Fed. Reg. 42007 (August 1, 2007).
[7] *Id* at 42008.
[8] *Id.*